IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FEDERAL TRADE COMMISSION Plaintiff, v. SHIRE VIROPHARMA INC. Defendant.	:	C.A. No. 1:17-cv-00131-RGA

REPLY BRIEF IN FURTHER SUPPORT OF
MOTION TO DISMISS BY SHIRE VIROPHARMA INC.

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ViroPharma's opening brief established that the Complaint must be dismissed for two independently dispositive reasons. ***First***, the FTC has not alleged facts establishing that there is "reason to believe" ViroPharma "*is* violating, or *is about to* violate" the law, as required for the FTC to "bring suit in a district court" pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). ***Second***, the conduct at issue is categorically immune from antitrust scrutiny under the *Noerr-Pennington* doctrine. The FTC's current position that ViroPharma's conduct was a "sham" is directly at odds with the facts properly before the Court, including contemporaneous representations that the government made to other courts about the complexity of the scientific issues raised by ViroPharma's citizen petition, which the FTC chooses simply to ignore.

I. SECTION 13(b) DOES NOT AFFORD THE FTC A RIGHT OF ACTION

As explained in ViroPharma's opening brief, and as the FTC does not dispute, the FTC's power to act is limited to the statutory authority delegated to it by Congress. *See* D.I. 20, Opening Br. in Supp. of Mot. to Dismiss ("MTD") at 11. Because the FTC lacks authority to file this action pursuant to Section 13(b), the Court lacks jurisdiction to hear it. 28 U.S.C. § 1345 ("[T]he district courts shall have original jurisdiction of all civil actions . . . commenced . . . by any agency . . . expressly authorized to sue by Act of Congress.").

A. The FTC's Authority to "Bring Suit in a District Court" Is Limited to Cases in Which the Defendant "Is Violating" or "Is About to Violate" The Law

On its face, Section 13(b) requires the FTC to plead that ViroPharma "is violating, or is about to violate" a law enforced by the FTC in order to "bring suit in a district court of the United States to enjoin any such act or practice." 15 U.S.C. § 53(b). The statute is clear and unambiguous. Because the FTC has alleged neither an ongoing nor imminent violation of the FTC Act, the Complaint must be dismissed.

In its response, the FTC offers three competing interpretations of Section 13(b). *See* D.I. 22, Opp'n to Mot. to Dismiss ("Opp.") at 8-9, 9-11, and 19-20. None of those interpretations can be squared with the statute's express language.

1. The FTC's Flawed Interpretation No. 1: That It Has Authority to Sue in Federal Court in Any Case In Which It Seeks A Permanent Injunction

The FTC first argues that the language limiting its Section 13(b) authority to cases in which there is "reason to believe" that the defendant "is violating, or is about to violate" the law does not apply to suits seeking permanent injunctions. *See* Opp. at 8-9. That interpretation is not faithful to the text of Section 13(b).

Any statutory interpretation "begin[s], as [it] must, with a careful examination of the statutory text." *Henson v. Santander Consumer USA, Inc.*, 582 U.S. __ (2017), slip op. at 3. The FTC's authority to "bring suit in a district court of the United States" is defined in the first sentence of Section 13(b):

> Whenever the Commission has reason to believe . . . that any person, partnership, or corporation **is violating, or is about to violate**, any provision of law enforced by the Federal Trade Commission . . . the Commission . . . **may bring suit in a district court of the United States** to enjoin any such act or practice.

15 U.S.C. § 53(b) (emphasis added).

Ignoring this clear statement governing the limited circumstances in which the FTC "may bring suit" in federal court, the FTC focuses instead on a subsequent proviso in Section 13(b) that allows the FTC, once properly in federal court, to seek a permanent injunction where warranted. *See id.* ("*Provided further*, that in proper cases the FTC **may seek**, and after proper proof, the court may issue, a permanent injunction.") (emphasis added). If Congress intended that proviso to be an independent grant of authority to sue in federal court in any case where the FTC seeks a permanent injunction regardless of the need for immediate relief, as the FTC argues, it would have used the same language concerning "bring[ing] suit" that it used in the first

sentence of Section 13(b). It did not. *See Henson*, slip op. at 6 ("And, usually at least, when we're engaged in the business of interpreting statutes we presume differences in language . . . convey differences in meaning.").

Moreover, the FTC's interpretation would effectively eliminate any limitation on its ability to sue in federal court, because the FTC presumably would seek some injunctive relief in every case regardless of whether the violation was in the past, present, or future. That interpretation would also render the first sentence of Section 13(b) a nullity, because the right to seek a permanent injunction implies a right to seek a preliminary injunction as well. *See, e.g.*, *FTC v. H.N. Singer, Inc.*, 668 F.2d 1107, 1111 (9th Cir. 1982) ("It is clear that, because the district court has the power to issue a permanent injunction to enjoin acts or practices that violate the law enforced by the Commission, it also has authority to grant whatever preliminary injunctions are justified by the usual equitable standards . . . ."). It is a basic canon of statutory construction that the Court must avoid constructions that render portions of statutes superfluous or a nullity. *Rosenberg v. XM Ventures*, 274 F.3d 137, 141 (3d Cir. 2001) (a statute must be interpreted so as to "give meaning to every word which Congress used" and to "avoid an interpretation which renders an element of the language superfluous").

Given the clear statutory language, it is not surprising that none of the cases the FTC cites hold that the "is violating, or is about to violate" limitation is inapplicable in cases in which the FTC seeks a permanent injunction. Indeed, the FTC does not – and cannot – cite a single decision holding that it is authorized under Section 13(b) to invoke the jurisdiction of the federal courts in the absence of misconduct that "is" or "is about to" occur.[1]

[1] The FTC cites *FTC v. Virginia Homes Manufacturing Corporation*, 509 F. Supp. 51 (D. Md. 1981), to suggest the "is violating, or is about to violate" requirement need not be met for the FTC to seek a permanent injunction. *See* Opp. at 9. However, the court in that case declined to decide whether the FTC may seek a permanent injunction on the basis of past misconduct because the FTC had also alleged *ongoing* misconduct. 509 F. Supp. at 55.

The cases cited by the FTC in which courts have recognized that it need not have filed an administrative complaint before seeking a permanent injunction[2] do not support the expansive authority the FTC seeks here. In those cases, the courts were not asked, and did not decide, whether the FTC had authority to sue in federal court in the absence of ongoing or imminent misconduct. Rather, they simply concluded that Section 13(b) does not impose a separate requirement that the FTC file an administrative proceeding before seeking a permanent injunction once the jurisdiction of the federal courts has been properly invoked. *See, e.g.*, *JS&A Grp., Inc.*, 716 F.2d at 457. Of course, that conclusion makes sense; once the FTC is properly in federal court because of the need for immediate action, it would serve no purpose to require it to conduct an administrative proceeding before returning to court to seek a permanent injunction.

The FTC's policy arguments also do not help its cause. First, the Court cannot and should not consider policy arguments when, as here, the statutory text is clear and unambiguous. *Henson*, slip op. at 8-9. Second, the arguments are wrong. The FTC claims that its enforcement agenda will be hampered if its authority to bring suits in federal court is limited to cases in which the defendant "is violating, or is about to violate" the law. Opp. at 12.[3] That argument ignores the primary enforcement authority granted to the FTC by Congress: its authority to bring

[2] *See United States v. JS&A Grp., Inc.*, 716 F.2d 451 (7th Cir. 1983); *H.N. Singer, Inc.*, 668 F.2d 1107; *FTC v. Commonwealth Mktg. Grp., Inc.*, 72 F. Supp. 2d 530 (W.D. Pa. 1999).

[3] The FTC mischaracterizes its own suits. In each of the cases that the FTC claims it would be precluded from pursuing, the complaints contained allegations of an ongoing violation. *See* Compl. ¶ 5, *JS&A Grp., Inc.*, 716 F.2d 451 (complaint alleged defendant corporation's president directed serial violations of FTC mail order rules and continued to "formulate[], direct[], and control[] the policies, acts, and practices" of the corporation); Am. Compl. ¶ 13, *H&N Singer, Inc.*, 668 F.2d 1107 (complaint alleged defendants' violations of FTC franchising rules were "continuing" at the time of suit); *Commonwealth Mktg. Grp., Inc.*, 72 F. Supp. 2d at 533-34 (describing the FTC's pursuit of injunctive relief the day before raiding defendant's offices to seize evidence of ongoing fraud); *Va. Homes Mfg. Corp.*, 509 F. Supp. at 52-53 (recounting defendant's ongoing refusal to notify warranty holders that their warranties had been modified to correct misleading terms). The FTC laments that under ViroPharma's "myopic" reading of Section 13(b) it could not have brought an action in district court against Volkswagen following the "Clean Diesel" scandal. *See* Opp. at 12. But in that case the FTC's complaint alleged not only that Volkswagen continued to sell defective cars at the time the complaint was filed, but that the harm to the environment was ongoing. *See* D.I. 1, Compl. ¶¶ 21, 38, *FTC v. Volkswagen Grp. of Am., Inc.*, No. 3:16-cv-01534-CRB (N.D. Cal. Mar. 29, 2016). The complaints in *JS&A Group, Inc.* and *H&N Singer, Inc.* are only available in hard copy from the court archives; they are included as Tab 1 and Tab 2, respectively, of the Appendix filed herewith.

administrative enforcement proceedings pursuant to Section 5 of the FTC Act and to issue binding cease and desist orders in cases where the defendant "has been or is using any unfair method of competition." 15 U.S.C. § 45(b).

That administrative authority was intended by Congress to be the primary means through which the FTC fulfills its enforcement mission. Indeed, it was the *only* authority granted the FTC for the first several decades of its existence. Congress expanded that authority in 1973 to allow the FTC to sue in federal court to address a specific perceived problem. Although Section 5 is fully capable of remedying past misconduct, the ability of the administrative process to address ongoing unlawful conduct was viewed as inadequate because it took too long. Congress thus enacted Section 13(b) to "permit the [FTC] to bring an immediate halt to unfair or deceptive practices when . . . . [a]t the present time such practices might continue for several years until agency action is completed." S. Rep. No. 93-151, at 30 (1973); *see also* MTD at 13-14, n.11. The FTC makes no mention of this legislative history, much less offers a competing view.

2. The FTC's Flawed Interpretation No. 2: That It Need Only Allege A "Cognizable Danger" of Recurrent Violation At Some Point in the Future

The FTC alternatively argues that it has authority to sue in federal court so long as it can allege a "cognizable danger of recurrent violation." Opp. at 9-11. Once again, the FTC's position is not faithful to the text of Section 13(b), which specifically addresses conduct that is occurring or is about to occur, not whether there is some "cognizable danger" that a violation will occur at some point in the future.

Neither of the Section 13(b) cases that the FTC cites to support this alternative interpretation holds that the FTC has the authority it seeks. *See id*. at 10-11. One of the cited cases involved challenges to the relief the FTC sought, claiming that facts justifying that relief had not been alleged. *See FTC v. Engage-A-Car Servs., Inc.*, No. 86-3758, 1986 WL 15066, at

*5 (D.N.J. Dec. 18, 1986).[4] The other case applied a likelihood of recurrence standard that the *defendants* urged on the court, without considering the dictates of Section 13(b). *See FTC v. Citigroup Inc.*, 239 F. Supp. 2d 1302, 1305-06 (N.D. Ga. 2001).

The FTC argues that ViroPharma's "interpretation of Section 13(b)'s permanent injunction proviso makes no sense" because it would "create situations when the [FTC] has made a showing that it can obtain injunctive relief but does not have standing to sue for such relief." Opp. at 11 (citation omitted). But there is no illogic in Congress's express limitations on the FTC's authority under Section 13(b). Where a defendant "*has been*" or "*is*" violating the law, the FTC may initiate an administrative proceeding under Section 5, as it has always done, and later seek to enforce its orders in district court. 15 U.S.C. § 45(b). By contrast, the FTC may only invoke its limited Section 13(b) authority where there is a need for immediate relief that cannot await the outcome of the administrative process: *i.e.*, where the defendant "*is* violating, or *is about to* violate" the law. *See FTC v. Evans Prods. Co.*, 775 F.2d 1084, 1087-88 (9th Cir. 1985); *FTC v. Merch. Servs. Direct, LLC*, No. 13-CV-0279-TOR, 2013 WL 4094394, at *3 (E.D. Wash. Aug. 13, 2013).[5]

[4] The FTC also relies on various cases brought by the SEC that likewise addressed questions about the "standard to determine if an injunction should issue," Opp. at 11, rather than whether the agency had authority to sue in federal court in the first place.

[5] Congress's amendment of the Investment Advisors Act of 1940 ("'40 Act") shortly before Section 13(b) was enacted is instructive. Prior to 1960, the '40 Act allowed the SEC to seek an injunction in federal court only where the defendant "*has* engaged or *is about to* engage" in a violation of law. Recognizing that that language did not "specifically provide that the [SEC] may bring an action for an injunction when it appears that any person *is engaged* in prohibited acts," H.R. Rep. No. 2179, at 8 (1960), Congress amended the statute to permit the SEC to seek an injunction where the defendant "*has* engaged, *is* engaged, or *is about to* engage" in misconduct. *See* 15 U.S.C. § 80b-9(d) (emphasis added). Clearly, Congress could have used this same "past, present, future" structure in Section 13(b) if it intended to give the FTC authority to sue in federal court based on past conduct, but did not.

3. The FTC's Flawed Interpretation No. 3: That There Are No Limits On Its Authority to File Suits in Federal Court For "Monetary Equitable Relief" Regardless of The Need For An Injunction

Finally, the FTC asserts a position that is even further removed from the actual text of Section 13(b), claiming it may sue in federal court for "monetary equitable relief" "[e]ven without a likelihood of recurrence." Opp. at 19-20. This remarkable argument suffers from the same error as the FTC's other arguments: it confuses and conflates the standards governing the Court's authority to order relief once it has jurisdiction with the standards governing the FTC's authority to file a lawsuit in federal court pursuant to Section 13(b).

The FTC's reliance on cases in which some relief other than an injunction was ultimately granted, even though injunctive relief was denied, are entirely inapposite. ViroPharma's motion challenges the ***FTC's*** authority to file this action in the first place. The question of whether the ***Court*** has authority to grant some remedy other than those specified in the statute once its jurisdiction has been properly invoked (a dubious proposition in light of recent Supreme Court precedent) remains for another day, should this case proceed beyond the Rule 12 stage.[6] Simply put, the FTC has not paid the price of admission necessary to get to that question.

B. The Complaint Does Not Satisfy Even The FTC's Relaxed Pleading Standard

Plainly, the reason that the FTC strains to re-write Section 13(b) is because it cannot satisfy the statute's express requirements. But, even if the statute were rewritten to replace "about to" with "cognizable danger of recurrent violation at some point in the future," or to

[6] The Supreme Court recently held in an analogous case considering an SEC disgorgement action that disgorgement is a penalty rather than an equitable remedy. *See Kokesh v. SEC*, 581 U.S. __ (2017). The question presented in *Kokesh* was whether a 5-year statute of limitations for government actions seeking a "civil fine, penalty, or forfeiture" applied to actions that, like this case, seek disgorgement. The Court unanimously held that it did because disgorgement was punitive. Although the Court was not asked to address and did not decide whether a statutory provision exactly like FTC Act Section 13(b) that makes no mention of the authority to seek disgorgement could be construed to grant such authority at all, *see id*. slip op. 5 n.3, at least five Justices expressed skepticism at oral argument. *See, e.g.*, Tr. of Oral Arg. at 31-32 (argued Apr. 18, 2017) (Roberts, C.J., questioning whether Congress had authorized the SEC to seek disgorgement, or whether "it's something that the government kind of devised on its own"); *see also id*. at 7-8 (Kennedy, J.); 9 (Sotomayor, J.); 13, 15-16 (Alito, J.); 52 (Gorsuch, J.). The transcript of oral argument in the *Kokesh* case is included at Tab 3 of the Appendix.

permit the FTC to sue in federal court whenever it can plead a basis for a permanent injunction, the Complaint still fails. The FTC cannot point to a single allegation in its Complaint plausibly suggesting that ViroPharma is likely to violate the law. In its response, the FTC relies heavily on its allegations regarding conduct that occurred years ago, but it concedes that such allegations are insufficient to meet the standard it advocates. *See* Opp. at 15 ("To be sure, the mere *existence* of some past violation does not standing alone justify injunctive relief."). That leaves the FTC to rely upon just two conclusory and legally-insufficient allegations in its Complaint. *See id*. at 14 (citing Compl. ¶ 150 (asserting a "cognizable danger" that ViroPharma will engage in misconduct in the future); *id*. ¶ 151 (claiming ViroPharma "could" commit future misconduct because it has the "incentive and opportunity" to do so)); *see also* MTD at 14-16.

Tellingly, there are no allegations that ViroPharma has engaged in any similar conduct in the last five years, which alone puts the lie to the FTC's unsubstantiated assertions about potential future violations. The FTC does not dispute that ViroPharma (1) no longer owns the rights to Vancocin, and (2) is not alleged to have filed a single petition ("sham" or otherwise) with respect to any other product or issue before, during, or after the time period at issue in this case. *See* MTD at 17.

C. Recurrence Is Highly *Un*likely, If Not Impossible

Not only has the FTC – which has the burden here – failed to plead any likelihood that ViroPharma's alleged conduct will recur, but ViroPharma has proffered numerous bases on which the Court should reasonably conclude that no such conduct *could* occur.[7] Critically, even if there were some basis to allege that ViroPharma might try to delay generic entry of some unidentified product through sham petitioning in the future, an intervening change in the law

[7] The FTC does not dispute that the Court may properly consider the matters of public record cited in ViroPharma's motion to dismiss, including SEC filings and reports of federal agencies. *See* MTD at 3 n.1, 18 n.15.

prevents it. Congress's 2007 amendment of the Food, Drug, and Cosmetic Act ("FDC Act") eliminated any threat of improper delay in the generic approval process resulting from baseless petitioning. As explained in ViroPharma's opening brief, those amendments added FDC Act Section 505(q), 21 U.S.C. § 355(q), in which Congress directed that the FDA "*shall not* delay approval of a pending application . . . because of any request to take any form of action . . . unless . . . the [FDA] determines . . . that a delay is necessary to protect the public health." *Id*. at (q)(1)(A)(ii) (emphasis added); *see also* MTD at 17-18. Section 505(q) empowered the FDA to comply with that requirement by granting it the authority to summarily deny any petition submitted for the primary purpose of delaying approval of a generic application. *Id*. at (q)(1)(E). The FTC does not – and cannot – dispute the fact, established through the FDA's own reports to Congress, that no ANDA approval has been delayed as a result of supposedly baseless petitioning since the 2007 amendment. *See* MTD at 18-19. Instead, the FTC cites the generalized concerns expressed by the FDA that the change in the law has not "curbed the filing of frivolous petitions" nor permitted it to dispose of those petitions "without expending substantial amounts of resources." Opp. at 18. But, even accepting those statements as true, they do not contradict the factual reports to Congress showing the complete absence of *any* instance in which approval of an ANDA was delayed because of a sham petition.[8] The antitrust laws are concerned with harm to competition, not generalized concerns by a federal agency about the impact of alleged conduct on its budget. *See* MTD at 19 n.17.[9]

[8] It is not ViroPharma's position that the number of improperly delayed ANDAs is "small," as the FTC suggests. Opp. at 18. The FDA's reports to Congress show that the number is "zero." *See* MTD at 16-18.

[9] The FTC cites *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665 (E.D. Pa. 2014), to argue that "delay due to a sham citizen petition remain[s] plausible even after the enactment of Section 505(q)." Opp. at 18. But *Suboxone* said no such thing. Rather, it simply quoted verbatim from the complaint in that case the plaintiffs' allegation that the FDA cannot discern whether or not petitions raise public health concerns, *see* 64 F. Supp. 3d at 690-91 – an allegation not made here. What is more, the *Suboxone* court made no mention of – and apparently did not consider – the FDA's reports to Congress establishing that there have been *no* instances of undue delay due to sham petitioning since the enactment of Section 505(q).

Finally, the FTC seeks to circumvent the distinct *un*likelihood of future misconduct by claiming that an inquiry of this sort is premature at the pleadings stage. Opp. at 15-16. That assertion is simply not correct. Courts routinely assess the adequacy of allegations about future misconduct in evaluating motions to dismiss.[10] They do so for good reason: those allegations are an essential element of the FTC's claim. Indeed, the FTC itself concedes that, even under its standard, it bears the burden to proffer *some* allegation of a "cognizable danger of recurrent violation," *United States v. W.T. Grant Co.*, 345 U.S. 629, 633 (1953); failure to carry that burden must result in dismissal. *See* MTD at 15.

II. VIROPHARMA'S CONDUCT IS PROTECTED PETITIONING ACTIVITY UNDER THE *NOERR-PENNINGTON* DOCTRINE

The FTC's response to ViroPharma's showing that the Complaint must be dismissed because ViroPharma's conduct is immune from antitrust scrutiny under the *Noerr-Pennington* doctrine is similarly unavailing. The FTC has failed to plead a basis to apply the sham exception here.

A. The FTC Cannot Avoid *Noerr-Pennington* Scrutiny On A Motion to Dismiss

First, the FTC relies on a handful of non-binding decisions by other courts to argue that the question of whether ViroPharma engaged in sham petitioning cannot be resolved on a motion to dismiss. *See* Opp. at 22-23, n.17. The Court should reject that contention out of hand.

The authority that the FTC cites is directly at odds with decisions of the Supreme Court, the Third Circuit, and this Court. *See, e.g.*, *Prof'l Real Estate Inv'rs Inc. v. Columbia Pictures*

[10] *See, e.g., In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 210 (S.D.N.Y. 2012) (granting motion to dismiss on grounds that plaintiff's allegations of a likelihood of future misconduct were "wholly speculative"); *In re Ductile Iron Pipe Fittings Indirect Purchaser Antitrust Litig.*, No. 12-169, 2013 WL 5503308, at *6 (D.N.J. Oct. 2, 2013) (dismissing claim on grounds that "past exposure to illegal conduct does not itself show a present case or controversy") (citation and alteration omitted); *In re Plavix Indirect Purchaser Antitrust Litig.*, No. 1:06-cv-226, 2011 WL 335034, at *4 (S.D. Ohio Jan. 31, 2011) ("[M]ere[] speculat[ion] that Defendants' previous behavior . . . leads to the assumption that Defendants will engage in [similar future behavior]" is insufficient to survive a motion to dismiss).

Indus., Inc., 508 U.S. 49, 63 (1993) ("*PRE*") ("[A] court may decide probable cause as a matter of law."); *Hanover 3201 Realty, LLC v. Village Supermarkets Inc.*, 806 F.3d 162, 202 (3d Cir. 2015) (Greenberg, J., dissenting on other grounds) ("Where the complaint fails at least to raise a question of fact on a sham petitioning issue, a court may reject the claim by granting a motion to dismiss."); *Arthrocare Corp. v. Smith & Nephew, Inc.*, No. 01-504-SLR, 2004 WL 896002, at *4 (D. Del. Mar. 10, 2004) (granting motion to dismiss under *Noerr-Pennington* where defendant's initiation of prior legal proceedings was a "legitimate attempt" to vindicate its interests).[11]

Moreover, the FTC's position – that application of *Noerr-Pennington* may be considered only after the defendant has endured expensive and burdensome discovery – is directly at odds with the doctrine's basic aim of "prevent[ing] any undue chilling of First Amendment activity." *Hanover 3201 Realty*, 806 F.3d at 180; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007) (recognizing the importance of addressing the adequacy of antitrust complaints before "allowing a potentially massive factual controversy to proceed") (citations omitted).

B. The FTC Cannot Evade The "Objectively Baseless" Standard By Labeling ViroPharma's Conduct A "Pattern"

The *Noerr-Pennington* doctrine affords those who exercise their First Amendment right to petition the government "broad immunity" from antitrust liability. *Hanover 3201 Realty*, 806 F.3d at 178. The FTC bears the burden of alleging and ultimately proving that ViroPharma's petitioning falls within the "very narrow scope" of *Noerr-Pennington*'s sham exception. *Trs. of Univ. of Pa. v. St. Jude Children's Research Hosp.*, 940 F. Supp. 2d 233, 245, 247 (E.D. Pa. 2013) (citation omitted); *see also* MTD at 21. As both parties acknowledge, the sham exception

[11] The single unpublished District of Delaware case cited by the FTC asserts that the question of whether underlying litigation is baseless is a "factual issue." *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 3860680, at *6 (D. Del. Aug. 31, 2011). In that case, however, the baselessness inquiry involved a counterclaim for which there was no record of any kind, and would have required the court to determine the validity of a complex patent. *See id*. Clearly, this Court is permitted to consider facts at the motion to dismiss stage, so long as those facts are properly before it. *See Hartig Drug Co. Inc. v. Senju Pharm. Co. Ltd.*, 836 F.3d 261, 268 (3d Cir. 2016).

is analyzed somewhat differently depending on whether the defendant has engaged in a "pattern" of "sham" petitions. *Compare PRE*, 508 U.S. at 60 (a single petition must be "objectively baseless"), *with Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 512-13 (1972) (a pattern of petitions must have been filed "with or without probable cause, and regardless of the merits" such that the "administrative and judicial processes [were] abused"). Here, there should be no doubt that ViroPharma's petitioning was not a "pattern" designed to deprive potential rivals of access to administrative proceedings.

The FTC relies heavily on the framework the Supreme Court laid out in *California Motor*. However, that standard only applies to circumstances in which the defendant has launched a meritless, multi-front attack in order to block the plaintiff's access to the adjudicatory process and to drive up the plaintiff's cost of doing business. *See Cal. Motor Transp.*, 404 U.S. at 512 (describing defendant's efforts to "deprive the competitors of meaningful access to the agencies and courts"); *Hanover 3201 Realty*, 806 F.3d at 182 (requiring proof of a "policy of harassment with the effect of obstructing [plaintiff]'s access to governmental bodies" and the imposition of "significant expense"). Such circumstances are entirely absent here.

Although the FTC attempts to position this as a "pattern" case by mischaracterizing and double counting the number of filings at issue, ViroPharma filed *one* citizen petition with *one* regulator (the FDA) for *one* purpose (the continuation of the bioequivalence testing method). As ViroPharma explained in its opening brief, *all* of the additional filings alleged to have caused competitive harm were submitted in support of that single citizen petition directed to the federal agency charged with making the decision. *See* MTD at 26-29. No competitor to ViroPharma was a party to those proceedings, and there is no allegation that ViroPharma's petitioning imposed costs on competitors or obstructed their access to the FDA or any tribunal. In these

circumstances, it is not the *California Motor* framework, but the *PRE* "objectively baseless" standard, that applies.[12]

The FTC's arguments to the contrary are unpersuasive. For example, the FTC asserts that ViroPharma's petitioning should be subjected to a pattern analysis because its citizen petition filings were "strategically timed" to cause delay. Opp. at 25. The FTC's own allegations make clear, however, that ViroPharma made only three submissions on the citizen petition docket after July 2010, the earliest date that the Complaint alleges a generic form of Vancocin was ready for FDA approval, Compl. ¶ 147, and two of those three filings were separated by an eleven-month period in which no filings were made at all, *id*. ¶ 118. The FTC's only response to this fundamental flaw in its theory is to point to the vague assertion in the Complaint that generic entry might have occurred "even earlier" than July 2010. Opp. at 25-26 (citing Compl. ¶ 147). Not only is that assertion completely unsupported by any well-pled factual allegations, but it is contradicted by the position taken by the government in other proceedings that make clear that in late 2011 the FDA was still wrestling with the complex scientific issues regarding the appropriate bioequivalence standard to apply. MTD at 9-10, 25.

Likewise, the FTC urges the application of a *California Motor* pattern analysis on the basis of ViroPharma's lawsuits and public comments. Opp. at 24-25. As ViroPharma explained, however, the Complaint does not allege that any of these filings caused (or was even capable of

[12] *See, e.g.*, *Avaya Inc., RP v. Telecom Labs, Inc.*, 838 F.3d 354, 413-14 (3d Cir. 2016) (multiple claims in the same lawsuit treated as a single proceeding); *P.R. Tel. Co., Inc. v. San Juan Cable Co. LLC*, 196 F. Supp. 3d 248, 323 (D.P.R. 2016) ("[P]etitions and motions filed within the same litigation or proceeding . . . are not counted as separate proceedings for analysis under *PRE* or *California Motor Transport*."); *In re Flonase Antitrust Litig.*, 795 F. Supp. 2d 300, 312 n.14 (E.D. Pa. 2011) (multiple FDA filings on the same topic "comprise a single instance of petitioning the FDA"); *In re Terazosin Hydrochloride Antitrust Litig.*, 335 F. Supp. 2d 1336, 1360 (S.D. Fla. 2004) (separate lawsuits are part of the same proceeding where "they all involved the same patent and the same underlying legal issue"). The FTC's attempts to distinguish the multiple filings that may be made in a single lawsuit from multiple filings in support of a single citizen petition on the basis that there are procedural rules that govern litigation make no sense. Those procedural rules do not prevent multiple filings; and there is certainly nothing, for instance, in the litigation process that precludes asserting multiple claims for relief in a single lawsuit, which courts have also universally concluded must be evaluated under the *PRE* standard.

causing) delay. *See* MTD at 28-29. In response, the FTC cites to various inapposite allegations in its Complaint. Opp. at 25 (citing Compl. ¶¶ 1, 53, 68, 128, 144, 147-49). However, other than a passing reference to "regulatory and court filings" in paragraph 1, none of these allegations even mentions ViroPharma's lawsuits or public comments, much less alleges facts as to how they may have caused delay or other anticompetitive effects. The FTC's argument is reduced to the basic allegation that ViroPharma's ***single*** citizen petition (and the supplements thereto) caused competitive harm – the quintessential set of facts to which *PRE*'s objective baselessness inquiry applies.

C. ViroPharma's Conduct is Immune Under Either Standard

Regardless of whether this case is viewed as involving a single petition under *PRE*, or a series of petitions under *California Motor*, the Court must evaluate whether ViroPharma had "*probable cause*" to believe that it had some (even if small) chance of success. *See PRE*, 508 U.S. at 62 ("The existence of probable cause to institute legal proceedings precludes a finding that an antitrust defendant has engaged in sham litigation."); *Cal. Motor Transp.*, 404 U.S. at 512-13 (holding that a pattern of baseless petitions may be considered a sham, even if some prove to have merit, if the overall pattern is to institute proceedings "without probable cause"). The probable cause determination is objective and "requires no more than a reasonable belief that there is a chance that a claim may be held valid upon adjudication." *PRE*, 508 U.S. at 62-63 (citation, internal quotation marks, and alterations omitted); *see also* MTD at 21-22.

The FTC argues that ViroPharma's filings were shams because ViroPharma did not submit "supporting clinical data" despite the advice of its consultants that it should and thus supposedly "knew that its petitioning campaign was *unlikely* to persuade the FDA . . . ." Opp. at 5, 29 (emphasis added); *see also* Compl. ¶ 53 (alleging ViroPharma's subjective belief that the petitioning was "unlikely to succeed"). But that is not the standard. Under the law,

ViroPharma's petition was not a "sham" so long as, objectively, there was probable cause to believe that it *might* be successful. The FTC's allegations alone establish that ViroPharma had probable cause to believe that its petition might be successful. Most notably, the Complaint acknowledges that ViroPharma's position was one that the FDA itself had held for years. *See* Compl. ¶ 43. It could not have been objectively unreasonable for ViroPharma to believe that the FDA could be convinced to return to its own standard. The Complaint also pleads facts establishing that the FDA viewed the question of the appropriate bioequivalence standard as highly complex, even deeming it necessary to convene two separate independent advisory committees to consider the issue. *Id*. ¶¶ 70-72, 80-85. Likewise, in separate federal court filings years after the petition was filed, the FDA repeatedly represented that it still had not decided whether to accept the arguments made by ViroPharma and adopt the bioequivalence standard it urged. *See* MTD at 25. Surely, if ViroPharma's position was truly baseless it would not have taken the FDA six years and multiple panels of experts to figure that out.

III. CONCLUSION

For the reasons set forth in ViroPharma's motion to dismiss and this reply, the Complaint should be dismissed.

Respectfully submitted,

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